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| 09 530,935 | 09 29 2000 | Patrick Hearing | 3927-4133US2 | 1381 |

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Morgan & Finnegan
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EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1675

DATE MAILED: 05 19 2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,935

Applicant(s)

HEARING ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-17,19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,5,6,9 is/are allowed.
- 6) ☒ Claim(s) 4,7,10,11,12 and 15 is/are rejected.
- 7) ☒ Claim(s) 13,14,16,17 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

Claims 1-7, 9-17, and 19 are pending examination.

Applicants' traversal, the amendment to claims 1 and 4 in paper no. 16 filed on 3/3/03 is acknowledged and considered.

There was a discrepancy in the traversal on pages 2 and 3 for which claims were supposed to be cancelled. Examiner contacted applicants' representative, Dorothy Auth on 5/6/03 for clarification on whether claims 20-25 or 20-37 were supposed to be cancelled. On 5/7/03, Dorothy Auth called the examiner to confirm the cancellation of claims 20-37. Thus, the cancellation of claims 20-37 in paper no. 16 filed on 3/3/03 is acknowledged.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The oath lists priority to Application No. 60/081,867, filed on 4/15/1998 and Application No. 60/088,321, filed on 8/5/1998 and a specific reference to the prior applications in the first sentence of the specification is missing.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or

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continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Objections

Claim 19 is objected to because of the following informalities:

Claim 19 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may depend in alternative form only. Claim 19 depends from claim 9 **and** one of claims 6, 7, or 10. See MPEP § 608.01(n). Accordingly, the claim 19 not been further treated on the merits.

Claim Rejections - 35 USC § 101

Applicants' arguments, see paper no. 16, filed on 3/3/3, with respect to 101 rejection have been fully considered and are persuasive. The 101 rejection of claims 21-37 has been withdrawn because of the cancellation of claims 21-37.

Claim Rejections - 35 USC § 112

Applicants' arguments, see paper no. 16, filed on 3/3/3, with respect to 112 first paragraph written description rejection have been fully considered and are persuasive. The 112 first paragraph rejection of claims 21-37 has been withdrawn because of the cancellation of the claims.

Applicants' arguments, see paper no. 16, filed on 3/3/3, with respect to 112 first paragraph enablement rejection have been fully considered and are persuasive. The 112 first

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paragraph rejection of claims 9 and 19 has been withdrawn because applicants state that, "the instant invention is directed towards a viral vector delivery system and not to a method for treating a specific disease."

Applicants' arguments, see paper no. 16, filed on 3/3/3, with respect to 112 second paragraph rejection have been fully considered and are persuasive. The 112 second paragraph rejection of claims 1, 4, 5, and 21-25 has been withdrawn because of the cancellation of claims 21-25 and the amendment to claims 1 and 4. However, upon further consideration, a new ground(s) of rejection is made in view of the amendment to claim 4.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "propagating step for the helper adenovirus vector occurs in a first cell-line". There is insufficient antecedent basis for this limitation in the claim. The propagating step in claim 1 (from which claim 4 depends) requires propagating a DNA delivery adenoviral vector and helper adenoviral vector. Claim 4 only recites propagating the helper adenoviral vector.

Applicant's arguments with respect to claim 4 have been considered but are moot in view of the new ground(s) of rejection.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The claim does not define whether the A repeat VI element is part of SEQ ID NO: 1 or a COUP-TF binding site because of the comma after the term "sites". Suggest removing the comma after the term "sites" on lines 3 of the claim.

Applicant's arguments with respect to claim 7 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 11, 12, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmid et al. (IDS, J. Virol, 71: 3375-3384, 1997) as evident by Schmid et al. (IDS, J. Virol, 72:6339-6347, 1998). Schmid teaches an adenovirus serotype 5 vector comprising a packaging signal consisting of at least two copies of 5' TTTGN8CG-3' and an A repeat VI element. (Figure 1, page 3376). The AI, AII, and AV regions of the adenovirus vector anticipate at least two copies of 5' TTTGN8CG-3'.

Schmid does not specifically teach that the adenovirus serotype 5 packaging sequence contains the COUP-TF binding site (a repressor binding site). However, the COUP-TF binding site is naturally embedded in the adenovirus 5 packaging sequence as evident by Schmid (J.

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Viol, 72:6339-6347, 1998). Thus, the product taught by Schmid (1997) would anticipate the product in claim 11 because Schmid (1998) teaches that a COUP-TF binding site is naturally embedded in the adenovirus packaging sequence.

In addition, Schmid (1997) teaches that the adenovirus vector has a packaging sequence (AV or AVII) that is flanked by the repressor-binding site. Furthermore, Schmid teaches that the repressor-binding site is located between packaging sequences, AV and AVII (Fig. 1).

Applicants' arguments with respect to claim 10, 11, 12, and 15 have been considered but are moot in view of the new ground(s) of rejection.

Claim 10, 11, 12, and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Schmid et al. (IDS, J. Virol, 72:6339-6347, 1998). Schmid teaches an adenovirus serotype 5 vector comprising a packaging signal consisting of at least two copies of 5'TTTGN8CG-3' and an A repeat VI element. (Figure 1, page 6340). The AI, AII, AV and AVI regions of the adenovirus vector anticipate at least two copies of 5'TTTGN8CG-3'. Schmid further teaches that the adenovirus packaging element has a repressor binding site embedded in it and that the binding site interacts with COUP-TF (pages 6342-6344). In addition, Schmid teaches that the adenovirus vector has a packaging sequence (AV or AVII) that is flanked by the repressor-binding site. Furthermore, Schmid teaches that the repressor-binding site is located between packaging sequences, AV and AVII (Fig. 1).

Applicants' arguments with respect to claims 10, 11, 12, and 15 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Claims 1-3, 5-6, and 9 are free of the prior and are in condition for allowance.

Claims 13, 14, 16, and 17 are objected to for depending on a rejected claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

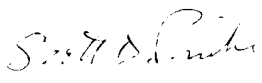
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635


SCOTT D. PRIEBE, PH.D.
PATENT EXAMINER